

Postoperative analgesic efficiency of transversus abdominis plane block after ventral hernia repair: a prospective, randomized, controlled clinical trial

Ion Chesov, Adrian Belfi

“Valeriu Ghereg” Department of Anaesthesiology and Reanimatology, “Nicolae Testemitanu” State University of Medicine and Pharmacy, Chisinau, Republic of Moldova

Abstract

Background and aims: Effective postoperative analgesia is a key element in reducing postoperative morbidity, accelerating recovery and avoiding chronic postoperative pain.

The aim of this study was to evaluate the effectiveness of ultrasound-guided Transversus Abdominis Plane (TAP) block, performed before surgical incision, in providing postoperative analgesia for patients undergoing open ventral hernia repair under general anaesthesia.

Methods: Seventy elective patients scheduled for open ventral hernia repair surgery under general anaesthesia were divided randomly into two equal groups: Group I received bilateral TAP block performed before surgical incision (n = 35); Group II received systemic postoperative analgesia with parenteral opioid (morphine) alone (n = 35). Postoperatively pain scores at rest and with movement, total morphine consumption and opioid related side effects were recorded.

Results: Postoperative pain scores at rest and mobilization/cough were significantly higher in patients without TAP block ($p < 0.05$). Mean intraoperative fentanyl consumption was comparable between the two groups: 0.75 ± 0.31 mg in group I (TAP) and 0.86 ± 0.29 mg in group II (MO), $p = 0.1299$. Patients undergoing preincisional TAP block had reduced morphine requirements during the first 24 hours after surgery, compared to patients from group II, without TAP block ($p = 0.0001$). There was no difference in the incidence of opioid related side effects (nausea, vomiting) in the both groups during the first 24 postoperative hours.

Conclusion: The use of preincisional ultrasound guided TAP block reduced the pain scores at rest and with movement/cough, opioid consumption and opioid-related side effects after ventral hernia repair when compared with opioid-only analgesia.

Keywords: ventral hernia, pain management, postoperative pain, transversus abdominis plane block

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Introduction

Postoperative pain is considered one of the worst complications after surgery, and inadequately post-

operative pain management continues to be a major challenge for clinicians, patients and their families [1]. Insufficient pain relief in the postoperative phase is a well-known serious public health problem worldwide [2].

The prevalence of postoperative pain, cited in the literature, varies considerably. Moizo et al. [3] reported an incidence of 2.2% for postoperative pain; Apfelbaum et al. [4] – 58%; Pyati and Gan [5] – 70%. Published data suggest that 80 percent of patients experience pain in the postoperative period, meanwhile 11-20% experiencing severe pain [4]. Mwaka et al.

Address for correspondence: Ion Chesov, MD
“Nicolae Testemitanu” State Univ.
of Medicine and Pharmacy
165 Stefan cel Mare si Sfânt Ave,
Chisinau, Republic of Moldova
E-mail: ion.chesov@usmf.md

reported a prevalence of postoperative pain of 58% at 30 minutes after surgery, 55.3% at 24 hours, and 34.7% at 48 hours [6]. Woldehaimanot et al. reported that incidence of pain at 72 hours after surgery was 91.4%, and 80.1% of the patients were undertreated [7]. Existing evidence suggests that less than half of patients experiencing pain after surgery report adequate postoperative pain relief [8].

In the last two decades, peripheral nerve blocks have gained considerable popularity for the management of acute postoperative pain after major surgery in adults and children, especially as a part of multimodal approach for postsurgical pain management. The Transversus Abdominis Plane (TAP) block is a relatively new promising regional anaesthesia technique that provides analgesia to the parietal peritoneum, skin and muscles of the anterior abdominal wall [9].

The aim of this study was to evaluate the effectiveness of ultrasound-guided TAP block, performed before surgical incision, in providing postoperative analgesia to patients undergoing open large ventral hernia repair (median eventration) under general anaesthesia, compared to conventional systemic analgesia with parenteral opioid alone.

Methods

This was a prospective, randomized, controlled clinical trial. The Research Ethics Committee of the “Nicolae Testemitanu” State University of Medicine and Pharmacy (Protocol No. 54 of 06/25/2014) approved the study protocol. Written informed consent was obtained from all patients enrolled in the study. The study was done at the Department of Anaesthesiology and Intensive Care, Institute of Emergency Medicine, Chisinau, Republic of Moldova, between July 2014 and February 2016. Seventy consecutive patients scheduled for elective incisional ventral hernia repair surgery under general anaesthesia were included in the study. Ventral hernia was defined as a bulge of tissue in the abdominal wall that occurred at a previous incision site (median eventration). In all cases the repair was performed by conventional “open” method via midline incision laparotomy. Exclusion criteria were: 1. Refusal of the patient; 2. Age younger than 18; 3. Emergency surgery; 3. Patients physical status class ≥ 4 according to the American Society of Anaesthesiology (ASA) classification; 4. Unconscious patient; 5. Hypersensitivity to bupivacaine and morphine. Patients were divided randomly (simple randomisation using a computer based random number generator) into two equal groups: Group I received standard general anaesthesia with bilateral TAP block performed before surgical incision ($n = 35$); Group II received standard general anaesthesia with systemic postope-

ratve analgesia with parenteral opioid (morphine) alone ($n = 35$). Perioperative standard clinical monitoring was performed, including heart rate, respiratory rate, respiratory volume, electrocardiogram, non-invasive arterial blood pressure, arterial oxygen saturation, end-tidal carbon dioxide monitoring and urine output. General anaesthesia was performed in all patients with thiopental, fentanyl; muscular relaxation was obtained with atracurium. Subjects received for premedication midazolam 0.1 mg/kg i.v. After induction of anaesthesia and endotracheal intubation, in patients of Group I bilateral TAP block was performed immediately before surgical incision using the “in plane” technique. The TAP block was performed under ultrasound guidance with a portable ultrasound machine (Mindray Ultrasound Diagnostic System M7, Shenzhen Mindray Bio-Medical Electronics CO., LTD, Nanshan, Shenzhen, R.P. China) with a 12 MHz linear probe. The needle – Vasofix Safety 18 G (B. Braun Melsungen AG 34209 Melsungen Germany) – was inserted at the mid-axillary line at the mid-distance between the lower costal margin and the iliac crest. Under direct visualization 1.0 mg/kg of 0.25% bupivacaine solution was injected on each side. Local anaesthetic volume was calculated based on the results of our previous cadaveric study [10] and according to the results of a systematic review that demonstrated superior analgesic outcomes with 15 ml of local anaesthetic or more injected per side compared with lesser volumes [9]. Thus, taking into account the type of surgery (open laparotomy with a mid-line incision) and the length of the median incision, in order to achieve the analgesic extension to the supraumbilical region, the total volume of local anaesthetic was 20-40 ml per each hemiabdomen and the total dose was calculated not to exceed 2 mg/kg.

A standardized postoperative analgesia with intravenous continuous (automatic syringe) morphine 20 $\mu\text{g}/\text{kg}/\text{hour}$ was initiated in the recovery room in group II. Continuous infusion of morphine was applied according to the local institutional protocol, immediately after the extubation of the patient. In both groups, when patients suffered from pain and requested additional analgesia, they received a supplementary titrated dose of morphine (bolus 1 mg, 15 min lockout, maximum dose 4 mg/h). Preoperatively, demographic characteristics for each patient: sex, age, height, weight, ASA group were registered. Intraoperatively, duration of surgery, duration of anaesthesia, length of surgical incision were recorded.

Postoperatively, patients registered pain scores, both at rest and movement (during cough) at 3, 6, 12, 24 h after surgery using a 100-mm VAS (0 mm = no pain and 100 mm = worst possible pain). Total morphine consumption within the first 24 hours after surgery was recorded. In addition, complications of TAP, bowel

function, and opioid related side effects as postoperative nausea and vomiting were assessed. The levels of patients' sedation immediately and at 3, 6, 12, 24 h after surgery were assessed using Ramsay score [11]. The starting point for postoperative outcomes assessment was when the patient was extubated awake.

The sample size was calculated using a corresponding equation for a study comparing two means [12]. In order to have 80% power and $p < 0.05$ the study required 32 patients per group. Considering a drop-out rate of 10%, the required size of group was 35 patients.

Descriptive statistics were used to report the demographic characteristics of patients and central tendencies for quantitative variables. Results were reported as absolute values, means, and standard deviations. Student's t-test was used for continuous variables and Chi-square for categorical variables. For multiple comparisons one way ANOVA was used; by pair's post-hoc analysis Duncan test was applied. SPSS 17.0.1 was used as statistical software (IBM Inc.,

Armonk, NY). $P < 0.05$ was considered as statistically significant.

Results

The flow chart of the study is shown in Figure 1.

Seventy patients, 46 males (65.7%) and 24 females (34.3%) aged between 54 and 81 years with a mean (SD) of 70.6 (7.6), were included in the study. There was no statistically significant difference in the demographics characteristics of patients between the two groups with respect to age, height, weight, BMI or ASA physical status. The preoperative characteristics of patients are summarized in Table 1.

Most patients undergoing surgical repair of ventral hernia (77.14%) belonged to risk ASA risk score class I and II (Table 1). The mean (SD) duration of anaesthesia was 152.43 (49.25) minutes in group I (TAP) and 160.71 (59.2) minutes in group II (MO), the differences between groups were statistically nonsignificant ($p > 0.05$). The mean (SD) length of surgical incision

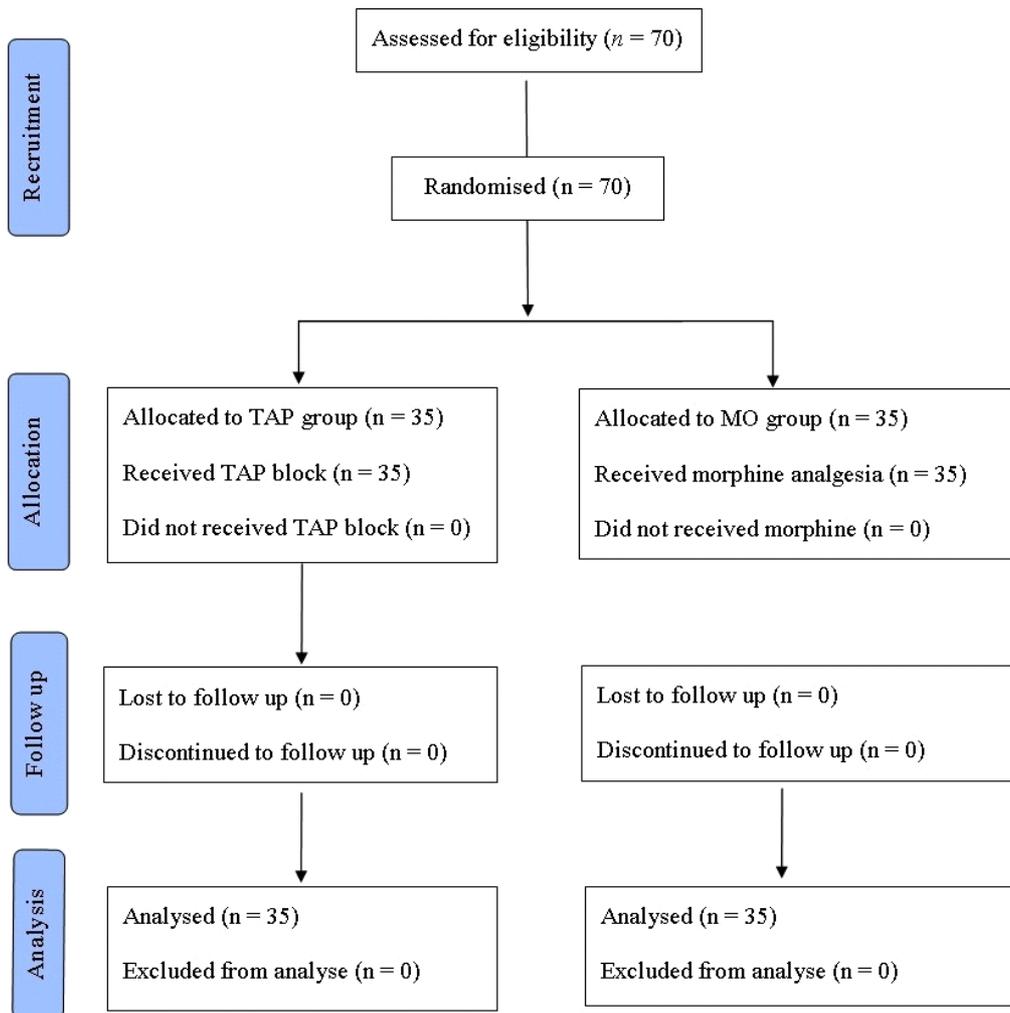


Fig. 1. Flow chart of the study

Table 1. Baseline characteristics and ASA physical status of patients

Criteria	Group I (TAP) n = 35	Group II (MO) n = 35	p-value
Male/female, n	23/12	23/12	-
Age, years *	69.8(8.0)	71.3(7.2)	0.4194
Weight, kg *	90.6(16.3)	88.9(15.7)	0.6714
Height, cm*	168.6(7.84)	168.8(8.2)	0.9172
BMI, kg/m ² *	31.8(5.3)	31.2(5.15)	0.6100
ASA I, %	8.57 (n = 3)	8.57 (n = 3)	1.00
ASA II, %	68.57 (n = 24)	68.57 (n = 24)	1.00
ASA III, %	22.86 (n = 8)	22.86 (n = 8)	1.00

Data are presented as a mean (standard deviation) for continuous variables; n or % for categorical

was 14.9 (6.75) cm in group I (TAP) and 15.8 (4.81) cm in group II (MO), $p = 0.5274$. Mean diastolic blood pressure values were comparable between the two groups ($p > 0.05$) during the first 24 hours after surgery. At the same time, systolic blood pressure and heart rates were higher in patients that did not receive transverse abdominal plane block ($p < 0.05$). Postoperative pain was measured using VAS scale (0-100) during rest and mobilization/cough. The pain scores in the postoperative period, during rest, were significantly lower in patients that received transverse abdominis plane block (Figure 2).

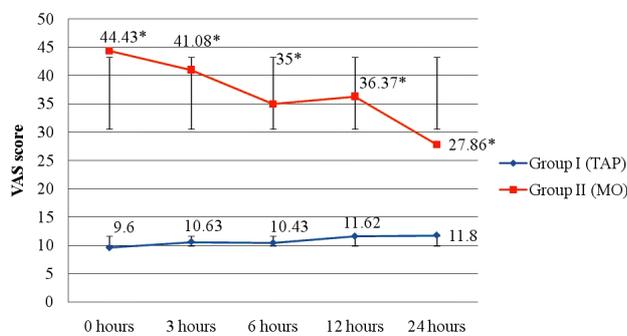


Fig. 2. Mean visual analog scale (VAS) pain scores at rest over the first 24 postoperative hours in patients after surgery for ventral hernia repair. Data are presented as a mean (standard deviation); * indicates significant difference in VAS scores between groups ($p < 0.05$)

Similarly, postoperative VAS pain scores at movement/cough were significantly lower in the TAP block group as compared with group II at 0, 3, 6, 12, and 24 hours after surgery (Figure 3). The number of patients with overall pain scores at rest and at cough/movement below 40 at 24 hours after surgery was significantly higher in TAP group ($p < 0.0001$). Mean (SD) intraoperative fentanyl consumption was comparable between the two groups of patients ($p = 0.1299$). At the same time, our study results showed that patients under-

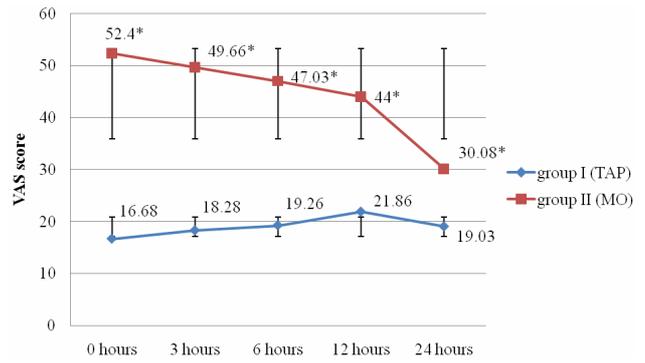


Fig. 3. Mean visual analog scale (VAS) pain scores on movement/caught over the first 24 postoperative hours, in patients after surgery for ventral hernia repair. Data are presented as a mean (standard deviation); * indicates significant difference in VAS scores between groups ($p < 0.05$)

going TAP block had a reduced mean total morphine requirements during the first 24 hours after surgery compared to patients from group II. Total intra- and postoperative opioid consumption is shown in Table 2.

Table 2. Intra- and postoperative opioid consumption in patients undergoing ventral hernia surgical repair

Opioid	Group I (TAP) n = 35	Group II (MO) n = 35	p-value
Intraoperative fentanyl, mg	0.75(0.31)	0.86(0.29)	0.1299
Mean postoperative morphine, mg	0	46.37(7.54)	0.0001

Data are presented as a mean (SD)

In the early postoperative period the mean sedation score was significantly lower in patients undergoing TAP block ($p = 0.0261$). There was no significant difference in the sedation scores at 3, 6, 12 and 24 hours postoperatively between the two groups of patients, as shown in Figure 4.

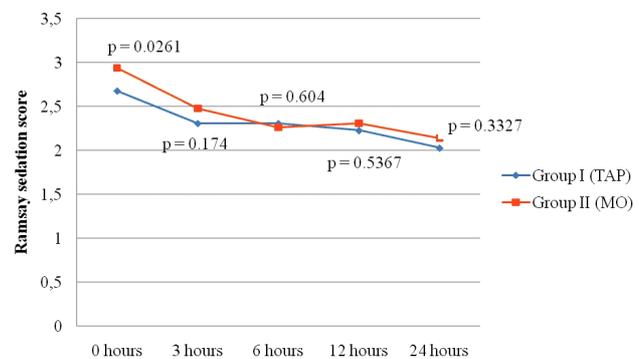


Fig. 4. Ramsay sedation score in the postoperative period in patients after ventral hernia surgical repair. Data are presented as a mean (SD)

There were no significant differences in the incidence of nausea and vomiting or headache between groups during first the 24 hours of postoperative period (Table 3). No patient in both groups reported pruritus. No complications were reported in relation to the administration of the TAP block under ultrasound guidance before surgical incision.

Discussion

Abdominal surgery represents one of the most painful types of surgery. Several authors reported that approximately 86% of patients experience postoperative pain after abdominal surgical interventions, 75% of them appreciate pain as moderate to severe [13]. Inadequately controlled postoperative pain carries potential adverse physiological and psychological consequences for patients, in addition to financial costs for caregivers and health care systems [14]. Poorly managed pain negatively affects the patient’s quality of life and functional recovery, increases the risk of post-surgical complications and the risk of persistent postsurgical pain, causes patient suffering and prolonged recovery, and may result in increased morbidity or mortality [8, 14].

Recent advances in pain control can provide many preoperative, intraoperative, and postoperative interventions and management strategies for managing postoperative pain. A variety of drugs, analgesic techniques and approaches are available, including patient-controlled analgesia, multimodal analgesia and pre-

emptive analgesia [1, 8]. Despite a variety of available pain medications and analgesic methods available, effective postoperative pain relief remains a challenge for anaesthesiologists. At the same time, the World Health Organization and International Association for the Study of Pain have recognized pain relief as a fundamental human right [15]. Uncontrolled postoperative pain may lead to complications and prolonged hospital stay and rehabilitation [14]. Thus, effective postoperative analgesia is a key element in reducing postoperative morbidity, accelerating recovery and avoiding chronic postoperative pain [16-18].

The transverse abdominis plane block has been previously described to be effective as a component part of multimodal postoperative analgesia in patients undergoing several lower abdominal procedures, such as caesarean section, hysterectomy, appendectomy, cholecystectomy, prostatectomy, colorectal surgery, etc. [19-22]. McDonnell et al., in a randomized double-blind study, evaluated the analgesic efficacy of transverse abdominal plane block in patients after abdominal surgery. The authors reported that the TAP block is effective for postoperative analgesia, reducing pain scores at rest and mobilization according to the visual analogue scale, during first 24 hours after surgery. In addition, the authors demonstrated that TAP block reduced the morphine requirements and sedation scores after surgery, the incidence of nausea and vomiting in the postoperative period [18]. Bjerregaard et al. reported that the TAP block is an effective method of analgesia following abdominal surgery, as part

Table 3. Incidence of anaesthesia/analgesia related side effects in the postoperative period in patients after ventral hernia open surgical repair

Time interval after surgery	Group I (TAP) n = 35		Group II (MO) n = 35		χ^2	p-value
	n	%	n	%		
Nausea/vomiting						
0 hours	2	5.71%	3	8.57%	0.213	0.6446
3 hours	1	2.86%	4	11.43%	1.910	0.1670
6 hours	1	2.86%	2	5.71%	0.342	0.5589
12 hours	0	0	1	2.86%	1.014	0.3138
24 hours	1	2.86%	1	2.86%	0.000	1.0000
Headache						
0 hours	1	2.86%	1	2.86%	0.000	1.0000
3 hours	2	5.71%	2	5.71%	0.000	1.0000
6 hours	2	5.71%	2	5.71%	0.000	1.0000
12 hours	1	2.86%	2	5.71%	0.342	0.5589
24 hours	1	2.86%	1	2.86%	0.000	1.0000
Pruritis						
0 hours	0	0	0	0	-	-
3 hours	0	0	0	0	-	-
6 hours	0	0	0	0	-	-
12 hours	0	0	0	0	-	-
24 hours	0	0	0	0	-	-

Data are presented as n or %

of multimodal analgesic regimens. The authors found lower pain scores at rest and during mobilization (coughing) at 4, 8, 12, 20, 26, and 36 hours after the operation. Additionally, the cumulative consumption of intravenous morphine was lower in the first 48 hours postoperatively in patients with abdominal transverse plane block [23]. Similarly, Charlton et al. found a significant decrease in pain scores and morphine consumption in the first 24 hours after abdominal surgery in patients with TAP block. The authors observed a decrease in the incidence of side effects such as postoperative nausea and vomiting in patients who had received a TAP block compared to the control group [22].

Al-Touny et al. studied the efficacy of TAP block after inguinal hernia repair. The authors reported a reduction in the total consumption of morphine by 39% after surgery in patients with TAP block, compared to patients in the bupivacaine-morphine group. No significant differences in the incidence of side effects such as nausea, vomiting, and sedation level were found between the groups of patients [24]. Fields et al. studied the efficiency of the TAP block in patients undergoing laparoscopic ventral hernia repair. The authors found that in the post anaesthesia care unit, the TAP group had significantly lower pain scores than the control group. Additionally, patients receiving TAP block used less opioids than the control group in the postoperative period. The authors found no significant difference in pain scores at 24 hours postoperatively [25].

There is a considerable debate about the best approach and coverage of TAP for each type of surgery [20, 21], and the execution of TAP block in post-incisional ventral hernia repair is very contradictory. Some authors believe that posterior TAP is best for lower abdominal surgeries, the subcostal TAP block is ideal for upper abdominal procedures, and the combined technique provides the greatest analgesic coverage [26]. A systematic review has shown that there was no evidence for analgesic efficacy of transverse abdominis plane block in procedures with mid-laparotomy [20].

Our study updates the data regarding bilateral pre-incisional ultrasound-guided TAP analgesic block for open ventral hernia repair (median eventration), previous data referring mainly to laparoscopic ventral hernia repair [25]. Our study included patients undergoing midline incisions as elective procedures for post-incisional ventral hernia repair (median eventration). Such procedures requiring midline incision are routinely performed in our institution. We consider important to underline the efficacy of TAP block in a category of patients who underwent larger open surgery of the abdominal wall with a mean incision length of 15 cm and with a mean duration of 150 minutes.

The results of our study demonstrated that abdominal transverse plane block, performed under ultrasound guidance, before surgical incision, is an efficient method for post-operative analgesia in patients undergoing open mid-line surgical repair of ventral hernia. Patients in Group I (TAP) registered lower values of systolic blood pressure and heart rates and this fact, might suggest that TAP block, performed before surgical incision, could prevent hemodynamic response to surgical stimuli. In our study, TAP block resulted in reduced pain scores and reduced postoperative morphine requirements in the first 24 postoperative hours compared with opioid-only regimen used in the control group. A possible explanation of higher pain scores in group II (MO), despite the administration of systemic analgesia with morphine, could be attributed to the inefficiency of our institutional pain management protocol, or in some cases to the opioid-induced abnormal pain sensitivity or paradoxical hyperalgesia in these patients. At the same time, the incidence of overall pain scores at rest and at cough/movement below 40 at 24 hours after surgery was significantly higher in the TAP group ($p < 0.0001$), which reflects an effective pain relief.

In contrast to other studies, our results showed a comparable intraoperative fentanyl consumption in both groups of patients. These findings could be explained by the fact that the onset of TAP sensory block appears to be relatively slow, taking up to 60 minutes to reach maximum effect [18]. Being placed at the start of surgery, we can suppose that sensory analgesia was not achieved at a satisfactory level during the operation and that the TAP block had no significant analgesic effect during surgery for open midline ventral hernia repair. Another explanation would be the fact that doses and frequency of administration of intravenous fentanyl during surgery were left exclusively to the anaesthetist's decision, which could be a source of bias.

There were non-significant differences in postoperative nausea and vomiting between the groups during 24 hours after open surgical ventral hernia repair. Similarly to our data, Charlton et al. have not observed a decrease in the incidence of side effects such as postoperative nausea and vomiting in patients who received a block TAP compared to the control group [22]. We did not find any significant differences in the incidence of headache or pruritus in the postoperative period in both groups of patients.

Surprisingly, sedation scores in our study were significantly lower only immediately after surgical intervention in patients undergoing pre-incisional TAP block. At 3, 6, 12 and 24 hours after surgery, sedation scores were comparable in both groups. Despite the higher morphine consumption in patients with systemic analgesia (group II), there was no increase in sedation

scores. One explanation would be the higher pain scores and postoperative nausea and vomiting which caused patients to feel more alert in the postoperative period. Our results are different from other studies which reported lower sedation scores in patients who received TAP block for abdominal surgery [18, 23].

Our study has some limitations. The assessment of pain scores and side effects were limited to 24 hours of postoperative period, though the analgesic efficacy of TAP block was suggested for up to 48 hours. The reason was that local protocol did not support that patients routinely require systemic opioid analgesia after 24 hours after surgery and enforced active mobilization of patients, which would have been uncomfortable in the presence of the morphine pump. Monitoring and assessment at 18 hours after surgery has not been performed, because this could disturb the patients during the night. The study could not be blinded as the Institutional Research Ethics Committee did not permit a sham intervention in the second group.

Conclusions

Transverse abdominis plane block performed under ultrasound guidance before the surgical incision, provided efficient postoperative analgesia after open mid-line surgical ventral hernia repair. The use of pre-incisional ultrasound guided TAP block reduced pain scores at rest and on movement/cough and opioid consumption after open postincisional ventral hernia surgery when compared with opioid-only analgesia. We conclude that ultrasound-guided TAP block performed before surgical incision offers a good guarantee as a part of a multimodal analgesic regimen for patients undergoing open mid-incision ventral hernia repair.

Conflict of interest

Nothing to declare

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